



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting for Software Developers on the Common Formats for Patient Safety Data Collection

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS)

ACTION: Notice of public meeting.

SUMMARY: AHRQ coordinates the development of sets of standardized definitions and formats (Common Formats) that make it possible to collect, aggregate, and analyze uniformly structured information about health care quality and patient safety for local, regional, and national learning. The Common Formats include technical specifications to facilitate the collection of electronically comparable data by Patient Safety Organizations (PSOs) and other entities. Additional information about the Common Formats can be obtained through AHRQ's PSO website at <https://pso.ahrq.gov/common-formats> and the PSO Privacy Protection Center's website at https://www.psoppc.org/psoppc_web/publicpages/commonFormatsOverview.

The purpose of this notice is to announce a meeting to discuss implementation of the Common Formats with software developers and other interested parties. This meeting is designed as an interactive forum where software developers can provide input on use of the formats. AHRQ especially requests participation by and input from those entities which have used AHRQ's technical specifications and implemented, or plan to implement, the Common Formats electronically.

DATES: The meeting will be held from 1:00 to 3:30PM Eastern on Thursday, December 16th, 2021.

ADDRESSES: The meeting will be held virtually.

FOR FURTHER INFORMATION CONTACT: Dr. Hamid Jalal, Medical Officer, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Rockville, MD 20857; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; E-mail: psa@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 to 299b-26 (Patient Safety Act), and the related Patient Safety and Quality Improvement Final Rule, 42 CFR Part 3 (Patient Safety Rule), published in the Federal Register on November 21, 2008, 73 FR 70731-70814, provide for the Federal listing of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information (patient safety work product) regarding the quality and safety of health care delivery.

The Patient Safety Act requires PSOs, to the extent practical and appropriate, to collect patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers. (42 U.S.C. 299b-24(b)(1)(F)). The Patient Safety Act also authorizes the development of data standards, known as the Common Formats, to facilitate the aggregation and analysis of non-identifiable patient safety data collected by PSOs and reported to the network of patient safety databases (NPSD). (42 U.S.C. 299b-23(b)). The Patient Safety Act and Patient Safety Rule can be accessed at: <http://www.pso.ahrq.gov/legislation/>.

AHRQ has issued Common Formats for Event Reporting for three settings of care – hospitals, nursing homes, and community pharmacies. As part of the agency's efforts to improve diagnostic safety and quality in healthcare, AHRQ is in the process of developing Common Formats for Event Reporting – Diagnostic Safety (CFER-DS). The CFER-DS is intended to help healthcare providers identify and report missed opportunities in the diagnostic process in a standardized manner across healthcare settings and specialties. Widespread use of the CFER-DS will make it possible to collect, aggregate, and analyze diagnostic safety-related information from healthcare providers across the country, which in turn can accelerate learning in this vital area of patient safety. Public comment has been received on a version 0.1 of the CFER-DS, and an Expert Panel convened by the National Quality Forum (NQF) is currently in the process of reviewing the public comments and providing feedback to AHRQ.

Federally listed PSOs can meet the requirement to collect patient safety work product in a standardized manner to the extent practical and appropriate by using AHRQ's Common Formats. The Common Formats are also available in the public domain to encourage their widespread adoption. An entity does not need to be listed as a PSO or working with one to use the Common Formats. However, the Federal privilege and confidentiality protections only apply to information developed as patient safety work product by providers and PSOs working under the Patient Safety Act.

Each version of the Common Formats is released with accompanying technical specifications, intended to provide direction to software developers and to PSOs that plan to submit data to the Patient Safety Organization Privacy Protection Center (PSOPPC) to ensure non-identification for transmission to the NPSD. For existing Common Formats for Event Reporting, technical specifications include the following:

- Data dictionary—defines data elements and their attributes (data element name, answer values, field length, guide for use, etc.) included in Common Formats;
- Clinical document architecture (CDA) implementation guide—provides instructions for developing a file to transmit the data from the PSO to the PSOPPC using the Common Formats;
- Validation rules and errors document—specifies and defines the validation rules that will be applied to the Common Formats data elements submitted to the PSOPPC;
- Common Formats flow charts—diagrams the valid paths to complete the formats (a complete event report);
- Local specifications—provides specifications for processing, linking, and reporting on events and details specifications for reports; and
- Metadata registry—includes descriptive facts about information contained in the data dictionary to illustrate how such data corresponds with similar data elements used by other Federal agencies and standards development organizations (e.g., HL—7, International Standards Organization (ISO)).

Agenda, Registration, and Other Information about the Meeting

The December 16, 2021 meeting will be an interactive forum designed to allow meeting participants not only to provide input but also to respond to the input provided by others.

The meeting agenda will include: an update of Federal efforts related to the PSO Program and Common Formats; discussion of the CFER-DS, including requesting feedback on planned technical support materials and general integration/implementation; and, planning for future meetings, including discussing potential topics of interest for regular future meetings with software developers. AHRQ requests that interested persons send an email to SDMeetings@infinityconferences.com for registration information. Before the meeting, an

agenda and logistical information will be provided to registrants. Prior to the meeting, AHRQ invites review of the CFER-DS which can be accessed through NQF's website at https://www.qualityforum.org/Common_Formats_for_Patient_Safety_Data.aspx.

Dated: November 9, 2021.

Marquita Cullom,

Associate Director.

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